NCRR FactSheet

NCRR:
A Catalyst
for Discovery

Clinical Research makes it possible to apply knowledge gained through basic research to the development of lifesaving drugs, devices, and therapies that protect the health of our nation's citizens. The Clinical Research area of the National Center for Research Resources (NCRR) helps translate scientific knowledge into effective patient care through its General Clinical Research Centers program, through career development opportunities for young physicians and dentists who are interested in conducting clinical research, and through the National Gene Vector Laboratories program.

General Clinical Research Centers (GCRCs)

In 1959 Congress authorized the GCRC program at the National Institutes of Health (NIH). Today the Clinical Research area of the National Center for Research Resources (NCRR) supports the GCRC program comprised of a national network of 73 clinical research centers located primarily at major U.S. academic medical centers. (See listing of GCRC locations on page 3.) These GCRCs provide a research infrastructure for clinical investigators who receive their primary research support from other NIH components, federal agencies, or peer-reviewed sources of support in the private sector. In addition, these centers are equipped to be flexible and responsive to changing scientific and economic environments and to unforseen research challenges. By putting these resources at the disposal of NIH-supported scientists and other researchers, the GCRC program promotes the mission of each NIH institute.

NCRR is a catalyst for discovery for NIH-supported investigations throughout the nation. It creates, develops, and provides a comprehensive range of human, animal, technological, and other resources to enable biomedical research advances.

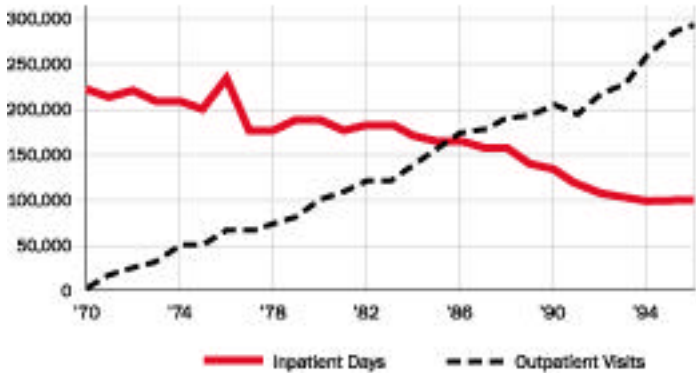
- Typically, NCRR-supported GCRCs are discrete units located within medical center hospitals. The GCRC network has been compared to a research-intensive hospital having several hundred beds distributed across the United States. These highly specialized environments allow biomedical investigators to safely and effectively conduct controlled patient studies, applying today's scientific discoveries to create tomorrow's life-saving therapies and cures. The GCRC program funds a broad range of resources at each center it supports. These include highly trained research personnel, inpatient and outpatient facilities and, in most instances, a core laboratory, a computerized database management and analysis system, and a metabolic kitchen. However, the individuality of each center is determined by the research strengths and needs of its host institution. The GCRC research staff, which provides a supportive environment for patients and helps investigators by facilitating the day-to-day research process, may include research nurses, dietitians, biostatisticians, skilled technicians, and administrative personnel.

- If an inpatient participating in a research protocol at a GCRC requires facilities that are not available within the GCRC but exist elsewhere at the host institution, the patient can be moved to a "scatter bed." This term refers to beds that are located outside the GCRC but are nevertheless supported by the GCRC program.

- While some U.S. research centers limit their focus to one disease, NCRR-supported GCRCs embrace a full spectrum of studies, including studies of AIDS, heart disease, cancer, diabetes, reproductive biology, nutrition, rehabilitation, aging, alcoholism, drug addiction, arthritis, infectious diseases, and mental disorders. In fiscal year (FY) 1996, approximately 7,800 research scientists pursued approximately 5,600 subprojects at NCRR-supported GCRCs.

Clinical Research Budget

Inpatient Days and Outpatient Visits at GCRCs



- The principal investigator (PI)—usually the dean of the medical school—is typically the recipient of a GCRC grant. The PI is responsible to NCRR for research conducted at the GCRC. With the aid of an institutional GCRC Advisory Committee and an appointed program director, the PI oversees the operation of the GCRC grant. It usually is awarded for a 3- to 5-year period and is renewable through competitive reapplication. The PI at each GCRC appoints advisory committee members, who are faculty familiar with the full range of the GCRC's research activities. The advisory committee supervises the center's management, approves eligible projects, and sets admission policies for research patients. The day-to-day supervision of GCRC activities is the job of the program director—an established physician-scientist who holds peer-reviewed grant support. The program director must be familiar with all research protocols and teach the concepts and methods of clinical research to fellows, residents, interns, and medical students.

- NIH-supported investigators and other scientists may request access to a GCRC facility by applying directly to the program director. However, priority is given to clinical research funded by the NIH. All studies conducted using a GCRC's resources require approval from the center's advisory committee.

- By providing GCRC infrastructure to NIH-supported researchers at no cost to them, NCRR leverages the effect of NIH research grant dollars awarded to these investigators by the NIH institutes. Access to GCRCs is available to investigators from all medical specialities, thus facilitating collaborative, interdisciplinary research opportunities. To ensure the diversity of a GCRC, no one group of investigators may utilize more than 33 percent of a GCRC's resources.

- Over the years, increasing numbers of NIH-supported researchers have come to depend on GCRC resources. NCRR's total FY1996 funding authority was $390 million. Approximately 38 percent of that funding was obligated by the Clinical Research area for the GCRC program and the National Gene Vector Laboratories (NGVLs) program. (See NGVLs program information on page 4.) From NCRR's total FY1997 authorization of $415 million, the Clinical Research area has been authorized an operating budget of just over $157 million, including $2 million for the NGVLprogram, which is supported in part by NCRR through the Clinical Research area.

Career Development NIH is a mainstay of career development and research training of health professionals. Several NCRR career-enhancement programs are administered under the GCRC program. They are described below. To be considered for participation in these programs, eligible individuals may apply directly to NCRR-supported GCRCs. There is no limit on the number of these applications that may be concurrently submitted or funded at each GCRC. Applications must be submitted by October 1 of each year, after which they are evaluated for scientific and technical merit in accordance with NIH peer-review procedures. The annual starting date for program funding is July 1 of each year. Program eligibility is restricted to U.S. citizens and individuals who hold permanent immigration visas. In addition, an applicant may not hold independent peer-reviewed grant support as a principal investigator prior to or concurrently with funding of these programs.

Clinical Associate Physician (CAP)

- The CAPprogram, which began in 1974, provides up to 3 years of early career support to physicians and dentists who want to become independent clinical investigators. Aparticipant in this program conducts research on GCRC-related projects under the guidance of an established clinical scientist. This work must account for at least 80 percent of the CAP's time and effort. Applicants must have an M.D. or D.D.S. degree, or its equivalent, have completed a residency program, and have at least 2 years of subspecialty (fellowship) training.

- In the first year, the CAPreceives a maximum salary of $50,000 plus fringe benefits. The salary increases by $5,000 for each of the second and third years of the award. The CAPmay receive supplemental salary from other sources, including NIH grants and contracts, but the salary request must be commensurate with institutional policies for individuals with comparable experience. Applicants may request up to $6,500 per year for scientific equipment, supplies, and domestic travel (not to exceed $1,000) to scientific meetings.

Minority Clinical Associate Physician (MCAP)

- The MCAPand CAPprograms are nearly identical. The MCAPprogram provides up to 3 years of support to minority physicians and dentists who want to become independent clinical investigators. In addition to the eligibility requirements set forth above, an MCAP applicant should be a member of a minority group that is determined by the grantee institution to be underrepresented in biomedical or behavioral research.

Clinical Research Scholar (CRS)

- The CRS program gives junior career development awards to physicians and dentists who want to pursue careers in patient-oriented clinical research but have had limited formal clinical research training. Applicants must have earned an M.D. or D.D.S. degree, or its equivalent, and completed at least 2 years of residency training at the time of the award. CRS applicants must be nominated by the GCRC Advisory Committee at their institution on the basis of qualifications, interests, accomplishments, motivation, and potential for performing high-quality, patient-oriented clinical research.

- The CRS program provides for 1 year of didactic course work and GCRC-related research activities conducted under the direction of a clinical investigator who is supported by peer-reviewed grants. The mentor must work with the candidate to select courses that complement laboratory and patient-oriented clinical research. Courses might include biostatistics, design of clinical trials, computer skills and bioethics, or topics related to more specific areas of clinical research. The courses and GCRC-related research must account for at least 90 percent of a participant's time and effort during the award period, and participants must have a supervised, patient-oriented clinical research experience.

- The CRS program provides salary up to $42,500 and associated fringe benefits for the 1-year award period. However, the request must be commensurate with institutional salary policies for individuals with comparable experience. Applicants may request up to $5,000 a year for supplies and domestic travel to scientific meetings.

General Clinical Research Centers Supported by NCRR

ALABAMA
University of Alabama

CALIFORNIA
Harbor General/University of California, Los Angeles Medical Center
Scripps Research Institute
Stanford University
University of California, Los Angeles
University of California, San Diego
University of California, San Francisco General Hospital
University of California, San Francisco, Moffitt Hospital--Adults
University of California, San Francisco, Moffitt Hospital--Children
University of Southern California

COLORADO
University of Colorado--Adults
University of Colorado Medical Center--Children

CONNECTICUT
University of Connecticut
Yale University--Adults
Yale University--Children

DISTRICT OF COLUMBIA
Howard University

FLORIDA
University of Florida

GEORGIA
Emory University

ILLINOIS
Northwestern University
University of Chicago

INDIANA
Indiana University

IOWA
University of Iowa

KENTUCKY
University of Kentucky College of Medicine

LOUISIANA
Tulane University/LSU Medical Center

MARYLAND
Johns Hopkins University
Johns Hopkins University, Bayview

MASSACHUSETTS
Beth Israel Hospital
Boston University
Brigham and Women's Hospital
Children's Hospital (Boston)
Massachusetts General Hospital
Massachusetts Institute of Technology
New England Medical Center Hospitals

MICHIGAN
University of Michigan

MINNESOTA
Mayo Foundation
University of Minnesota

MISSOURI
Washington University

NEW MEXICO
University of New Mexico

NEW YORK
Columbia University
Cornell University Medical College--Adults
Cornell University Medical College--Children
Mount Sinai School of Medicine--Adults
New York University
Rockefeller University
University of Rochester

NORTH CAROLINA
Bowman Gray School of Medicine
Duke University
University of North Carolina

OHIO
Case Western Reserve University
Children's Hospital--Cincinnati
Ohio State University

OREGON
Oregon Health Sciences University

PENNSYLVANIA
Children's Hospital of Philadelphia
Children's Hospital of Pittsburgh
Milton S. Hershey Medical Center, Pennsylvania State University
Temple University
University of Pennsylvania
University of Pittsburgh

SOUTH CAROLINA
Medical University of South Carolina

TENNESSEE
University of Tennessee
Vanderbilt University

TEXAS
Baylor College of Medicine--Children
University of Texas Health Science Center (Houston)
University of Texas Health Science Center (San Antonio)
University of Texas Medical Branch at Galveston
University of Texas Southwestern Medical Center (Dallas)

UTAH
University of Utah

VERMONT
University of Vermont

VIRGINIA
University of Virginia
Virginia Commonwealth University

WASHINGTON
University of Washington

WISCONSIN
Medical College of Wisconsin
University of Wisconsin School of Medicine

National Gene Vector Laboratories (NGVLs)

The ability of scientists to manipulate human genes is quickly moving from basic research laboratories to clinical studies at patients'bedsides. Since the first clinical gene therapy trial in 1990 that treated two immunodeficient children, approximately 120 more phase I protocols involving genetic manipulation have been initiated. Nevertheless, many issues remain to be resolved if this remarkable progress is to continue. One major concern is the availability of vectors used to transfer genes into target cells.

- The challenge of making large quantities of clinical grade vectors has been addressed by both academic institutions and private companies using standardized procedures and certified facilities. But these vectors are primarily for the use of their own investigators and generally are not available to outside researchers. Furthermore, these well-equipped organizations may not be able or willing to provide vectors for the unique protocols of outside investigators. For profit-driven, commercial organizations, the financial incentives lie in developing vectors for the treatment of common diseases. This means some academic investigators who have developed innovative protocols, or protocols to treat rare diseases, may have difficulty obtaining adequate quantities of clinical grade vectors for their studies.

- To establish a responsive resource to produce large quantities of clinical grade gene vectors for use by qualified investigators in approved phase I and II trials, in 1995 NCRR awarded three 5-year, renewable, cooperative agreements to establish NGVLs. The recipients, acknowledged experts in the field of gene therapy, were: Dr. Kenneth Cornetta of the University of Indiana, Indianapolis; Dr. Gary Nabel at the University of Michigan, Ann Arbor; and Dr. James Wilson at the University of Pennsylvania, Philadelphia. Under their direction, these NGVLs produce retroviral vectors, nonviral vectors, and adenoviral vectors, respectively. Operations of these laboratories are coordinated by the Indiana University NGVL.

- Requests for vectors are reviewed semiannually by the NGVLs' Scientific Review Board and the NGVLs' Steering Committee. The Steering Committee is composed of the NGVLs'directors, outside gene therapy experts, and representatives of NIH sponsoring organizations. These two groups evaluate the preclinical data, status of vector development, feasibility, protocol design, and qualifications of the applicant and the applicant's institution. Each approved vector is produced under Good Manufacturing Practice conditions and is safety-tested before distribution.

- The proposed clinical trial must be performed at a qualified domestic institution that may be for-profit or not-for-profit and public, private, or governmental. The institution must be capable of performing clinical research and of providing scientific support for the protocol.

- Funding of the NGVLs is shared by five NIH components: NCRR, the National Cancer Institute, the National Heart, Lung, and Blood Institute, the National Institute of Diabetes and Digestive and Kidney Diseases, and the Office of AIDS Research. NCRR oversees the NGVLprogram and administers its current $4.4 million annual budget.

Requests for applications should be directed to the Indiana University NGVL.

Additional information is available at:

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Current as of March 1997

Other available NCRR publications:

Clinical Research Resources

NCRR Highlights

NCRR Reporter

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